

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Effect of saffron powder on serum concentration of hs-CRP, TNF- $\alpha$ , MDA, TAC, adiponectin and leptin in patients with non-alcoholic fatty liver disease

#### Protocol summary

##### Summary

The present study is a double blind clinical trial. After approving the research in the ethics committee of the Vice-Chancellor of Research and Technology of Iran University of Medical Sciences and obtaining necessary permits, the participants from among the patients referred to Gastroenterology clinic of Rasoul-e-Akram Medical Center, That are based on liver ultrasound and blood tests, non-alcoholic fatty liver in them, who are willing to cooperate and enter the study, are selected and after explaining all stages of the research project and signing the consent form enter the design. At the beginning of the study, 15 cc of venous blood from patients will be taken after 10-12 hours of fasting, which will be freeze After separating the serum, it is freeze at -80 ° C. Public data forms (age, sex, Height, weight, BMI, waist circumference, hip circumference, smoking, duration of disease, fatty liver severity, blood pressure, etc.), the 24-hour recall of the feed and the IPAQ physical activity questionnaire are completed, as well as the patients Body fat percentage will be evaluated with ebody. At the end of the research, forms and measurements will be carried out again. Also, the weight loss regimen is individually adjusted for each person at the beginning of the study. Regarding the protocol for treating non-alcoholic fatty liver, a physical activity of 30 minutes, one day is recommended. Participants will be randomly divided into two groups: 1- An intervention group consisting of 38 males and females with non-alcoholic fatty liver who will receive 100 mg of saffron for 12 weeks during the study; . 2. Control group of Includes 38 males and females with non-alcoholic fatty liver that will be treated with placebo tablets containing dextrose malto during the intervention. The placebo will be in any shape, size, and color, and the packaging indistinguishable from saffron tablets. Inclusion criteria 1- Age 18 to 65 years 2. Both sexes 3. Detection of non-

alcoholic fatty liver by an expert physician based on the high levels of ALT, AST enzymes  $\geq 30$ U / L in men and  $> 19$ U/L in women) and liver transcription 4. Desire to participate in studying and signing conscientious intention Non-inclusion criteria: (exclusion criteria) 1- Pregnancy and lactation or planning pregnancy 2- Use an antioxidant supplement or any nutritional supplement within one month before sampling 3. Acute heart disease, kidney, thyroid, diabetes, infections, hepatitis B and C and other liver diseases (diagnosed by a specialist) and diseases that affect the weight (hyperprolactinemia, Cushing's syndrome) 4. Have a high-gain or weight loss regimen within 3 months prior to sampling 5- Using effective drugs on weight, fatty liver and insulin resistance during 3 months before sampling (hormonal, antidepressant, anti-psychotics) 6- Use of drugs that are probably related to NAFLD: 7- (valproic acid, tetracycline, systematic glucocorticoid, methotrexate, anabolic steroids, estrogen, tamoxifen or other known hepatotoxic drugs) Exit criteria: 1. Unwillingness to continue cooperation in research 2- Initiating the use of anti-NASH drugs (thiazolidinediones, vitamin E, betaine, milk thistle, UDCA, SAM-E, gemfibrozil, probiotic, anti-TNF- $\alpha$ ) 3. Start using any type of nutritional supplement and anti-inflammatory drugs 4. Cure for diseases that require special treatments that interfere with the intervention. 5- Pregnancy during the study 6- Patients whose compliance and consumption of saffron powder or placebo by them is less than 80% recommended by the host. Applied Objectives: If the effect of saffron powder on hs-CRP TNF- $\alpha$ , MDA, TAC, body composition, adiponectin and leptin (inflammatory and oxidative stress markers, body composition and adipokines) can be used as an auxiliary substance in Along with other treatments to improve disorders in patients with non-alcoholic fatty liver

## General information

### Acronym

### IRCT registration information

IRCT registration number: **IRCT201705309472N13**

Registration date: **2017-07-26, 1396/05/04**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

### Registration date

2017-07-26, 1396/05/04

### Registrant information

#### Name

Naheed Aryaeian

#### Name of organization / entity

Iran University of Medical Sciences

#### Country

Iran (Islamic Republic of)

#### Phone

+98 21 8670 4750

#### Email address

aryaeian.n@iums.ac.ir

### Recruitment status

**Recruitment complete**

### Funding source

Governmental/ iran university of medical science

### Expected recruitment start date

2017-02-18, 1395/11/30

### Expected recruitment end date

2018-10-23, 1397/08/01

### Actual recruitment start date

empty

### Actual recruitment end date

empty

### Trial completion date

empty

### Scientific title

Effect of saffron powder on serum concentration of hs-CRP, TNF- $\alpha$ , MDA, TAC, adiponectin and leptin in patients with non-alcoholic fatty liver disease

### Public title

Effect of saffron on inflammatory and antioxidant factors in patients with fatty liver disease

### Purpose

Supportive

### Inclusion/Exclusion criteria

Inclusion criteria 1- Age 18 to 65 years 2. Both sexes 3. Detection of non-alcoholic fatty liver by an expert physician based on the high levels of ALT, AST enzymes  $\geq 30$  U / L in men and  $> 19$  U/L in women) and liver transcription 4. Desire to participate in studying and signing conscientious intention Non-inclusion criteria: (exclusion criteria) 1- Pregnancy and lactation or planning pregnancy 2- Use an antioxidant supplement or any nutritional supplement within one month before sampling 3. Acute heart disease, kidney, thyroid, diabetes, infections, hepatitis B and C and other liver

diseases (diagnosed by a specialist) and diseases that affect the weight (hyperprolactinemia, Cushing's syndrome) 4. Have a high-gain or weight loss regimen within 3 months prior to sampling 5- Using effective drugs on weight, fatty liver and insulin resistance during 3 months before sampling (hormonal, antidepressant, anti-psychotics) 6- Use of drugs that are probably related to NAFLD: 7- (valporic acid, tetracycline, systematic glucocorticoid, methotrexate, anabolic steroids, estrogen, tamoxifen or other known hepatotoxic drugs) Exit criteria: 1. Unwillingness to continue cooperation in research 2- Initiating the use of anti-NASH drugs (thiazolidindiones, vitamin E, betaine, milk thistle, UDCA, SAM-E, gemfibrozil, probiotic, anti-TNF- $\alpha$ ) 3. Start using any type of nutritional supplement and anti-inflammatory drugs 4. Cure for diseases that require special treatments that interfere with the intervention. 5- Pregnancy during the study 6- Patients whose compliance and consumption of saffron powder or placebo by them is less than 80% recommended by the host.

### Age

From **18 years** old to **65 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **76**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

##### Street address

Shahid Hemmat Highway intersection of Sheikh Fazlollah and Shahid Chamran Iran University of Medical Sciences

##### City

tehran

##### Postal code

**Approval date**

2017-02-19, 1395/12/01

**Ethics committee reference number**

IR.IUMS.REC 1395.9411468008

**Health conditions studied****1****Description of health condition studied**

non alcoholic fatty liver disease

**ICD-10 code**

K76.0

**ICD-10 code description**

Fatty (change of) liver, not elsewhere classified

**Primary outcomes****1****Description**

hs-crp

**Timepoint**

Before intervention and 3 months after intervention

**Method of measurement**

ELISA kit in ng / ml

**2****Description**

ALT

**Timepoint**

Before intervention and 3 months after intervention

**Method of measurement**

Enzymatic photometric

**3****Description**

AST

**Timepoint**

Before intervention and 3 months after intervention

**Method of measurement**

Enzymatic photometric

**Secondary outcomes****1****Description**

Waist to hip ratio (WHR)

**Timepoint**

Before the intervention and three months after the intervention

**Method of measurement**

calculation

**2****Description**

TNF-a

**Timepoint**

Before the intervention and three months after the intervention

**Method of measurement**

ELISA kit in pg / ml

**3****Description**

TAC

**Timepoint**

Before the intervention and three months after the intervention

**Method of measurement**

Using the kits and colorimetric method in umol / L

**4****Description**

adiponectin

**Timepoint**

Before the intervention and three months after the intervention

**Method of measurement**

ELISA kit in ng / ml

**5****Description**

leptin

**Timepoint**

Before the intervention and three months after the intervention

**Method of measurement**

ELISA kit in ng / ml

**6****Description**

Malondialdehyde (MDA)

**Timepoint**

Before the intervention and three months after the intervention

**Method of measurement**

Colorimetric method ng / ml

**7****Description**

weight

**Timepoint**

Before the intervention and three months after the intervention

**Method of measurement**

Digital scale in kilograms

**8****Description**

body mass index (BMI)

**Timepoint**

Before the intervention and three months after the intervention

**Method of measurement**

Calculation / in kg / m2

## 9

### Description

Waist

### Timepoint

Before the intervention and three months after the intervention

### Method of measurement

Meter in cm

## 10

### Description

Hip circumference

### Timepoint

Before the intervention and three months after the intervention

### Method of measurement

Meter in cm

## 11

### Description

Body fat percentage

### Timepoint

Before the intervention and three months after the intervention

### Method of measurement

ebody device BIA method

## Intervention groups

### 1

#### Description

Saffron powder group: One day, one tablet will contain 100 mg of saffron for 3 months (12 weeks).

#### Category

Treatment - Drugs

### 2

#### Description

Placebo group: For a period of 3 months (12 weeks), one tablet will contain 100 mg dextrose malto.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

hazrat rasool akram hospital

##### Full name of responsible person

farnaz kaviani pour

##### Street address

Shahid Hemmat Highway intersection of Sheikh Fazlollah and Shahid Chamran Iran University of

Medical Sciences School of Public Health

#### City

tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Deputy of Research of Iran University of Medical Sciences

##### Full name of responsible person

Dr. Seyed Ali Javad Mousavi: Deputy of Research and Technology of Iran University of Medical Science

##### Street address

Shahid Hemmat highway, intersection of Sheikh Fazlollah and Chamran, Iran University of Medical Sciences

##### City

tehran

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Deputy of Research of Iran University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr naheed aryaean

##### Position

nutrition PHD

##### Other areas of specialty/work

##### Street address

Shahid Hemmat Highway intersection of Sheikh Fazlollah and Shahid Chamran Iran University of Medical Sciences School of Public Health

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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PhD in Nutrition Sciences, Assistant Professor

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

farnaz kaviani pour

**Position**

master student in nutrition sciences

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*